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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/739,262	12/19/2000	Brian K. Dieckgraefe	04255.00002	5851

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EXAMINER	
SOUAYA, JEHANNE E	
ART UNIT	**PAPER NUMBER**
1634	11

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/739,262	Dieckgraefe
Examiner	**Art Unit**
Jehanne Souaya	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 19, 2000* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *4-12 and 14-76* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *4-12 and 14-76* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 4-11, 14-22, 25-34, and 37-46, drawn to a method of diagnosing chronic inflammatory bowel disease, a method to aid in the differentiation of chronic mucosal injury from common acute inflammatory colon disorder and common non-inflammatory benign colon, a method to determine the degree of injury to small intestine or colon in patients with chronic mucosal injury, an a method of monitoring efficacy of therapy for chronic mucosal injury by detecting a REG gene expression product which is a protein, classified in class 435, subclass 7.1.

II. Claims 4-8, 12-~~19~~ 14-19, 23-31, 35-43 and 47-48, drawn to a method of diagnosing chronic inflammatory bowel disease, a method to aid in the differentiation of chronic mucosal injury from common acute inflammatory colon disorder and common non-inflammatory benign colon, a method to determine the degree of injury to small intestine or colon in patients with chronic mucosal injury, an a method of monitoring efficacy of therapy for chronic mucosal injury by detecting a REG gene expression product which is mRNA, classified in class 435, subclass 6.

III. Claims 49 and 50, drawn to a method of screening compounds for anti-mucosal injury activity by mixing a test sample with a REG gene expressing colonic cell, classified in class 435, subclass 6.

IV. Claims 51-75, drawn to a method of diagnosing ulcerative colitis and a method to aid in the differentiation of ulcerative colitis from common acute inflammatory colon disorder and common non-inflammatory benign colon by detecting expression of mRNA for HS.111244 by detecting mRNA for HS.111244, a method to determine the degree of injury to small intestine or colon in patients with ulcerative colitis by correlating the amount of HS.111244 expression with the degree of injury an and a method of monitoring efficacy of therapy for ulcerative colitis by quantitating HS.111244 expression and looking for a reduction over time of therapy classified in class 435, subclass 6.

V. Claim 76, drawn to a method of screening for compounds for anti-ulcerative colitis by mixing a test sample with a colonic cell expressing HS.111244 mRNA, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

A) The inventions of groups I and II are patentably distinct because the methods detect different products to achieve their objectives which are not obvious over one another. The methods of group I involve the detection of a polypeptide and rely upon a correlation between the expression of this polypeptide and inflammatory bowel disease. Alternatively, the methods of

group II involve the detection of an mRNA and rely upon the correlation between the expression of the mRNA and inflammatory bowel disease. The detection of expression of a polypeptide and its correlation to a disease is not obvious of the detection of expression of the mRNA encoding the polypeptide and its correlation to a disease because the mRNA and the polypeptide may be present at very different concentrations such that one is detectable while the other is not. Further, the reagents used to detect polypeptides and mRNA are different. Specifically, polypeptides can be detected with antibodies by detecting an antigen/antibody complex using methods such as Western blots, ELISAs and radioimmunoassays, while mRNAs are detected using complementary probes or primers that hybridize under annealing conditions. Consequently, the methods of groups I and II require different reagents, reaction conditions and reaction parameters and are unobvious over one another.

B) The methods of groups I & II are patentably distinct from the method of group III because these methods have different objectives, different methods steps and different reagents. The methods of groups I and II are methods of detecting expression of polypeptides or nucleic acids, respectively, of the REG gene family for the purposes of diagnosing inflammatory bowel disease, while the method of group III involves mixing cells already known to express a REG gene product with a test compound to determine whether the test compound decreases gene expression. Consequently, the method steps and reagents are different, making the methods of groups I & II novel and unobvious over the method of group III.

C) The methods of groups I and II are patentably distinct from the method of group IV and V because the methods are directed to different gene products. The methods of groups I and II are methods of detecting expression of a product of the REG gene family either by detecting protein or mRNA expression for the purpose of diagnosing inflammatory bowel disease while the methods of group IV is directed to detecting a patentably distinct expression product, namely the EST HS.111244 to detect a species of inflammatory bowel disease, ulcerative colitis. The expression of the REG family gene product are unobvious and unpredictable from the expression of the HS.111244 EST and its correlation to ulcerative colitis because these are structurally distinct nucleic acids. Further, the reagents, reaction components and objectives of the methods of groups I and II are different and unobvious over the methods of screening for a test compound using cells that express HS.111244 of group V.

D) The methods of group III is patentably distinct from the methods of groups IV and V because the methods have different objectives, different steps and require different reagents. The objective of the method of group III is to screen for compounds which have anti-mucosal injury activity using cells that express REG family gene products while the objective of the method of group V is to screen for compounds having anti-ulcerative colitis activity using cells that express HS.111244 mRNA. These nucleic acids are structurally and functionally distinct and compounds which have anti-mucosal injury activity may be different from compounds which have anti-ulcerative colitis activity. Further, the reagents, reaction components and objectives of the

method of group III, namely screening for test compounds, is different from the method of group IV which is detecting mRNA expression and diagnosing ulcerative colitis.

D) The method of group IV is patentably distinct from the method of group V because these methods have different objectives, different methods steps and different reagents. The method of group IV involves methods of detecting expression of HS.111244 nucleic acids for the purposes of diagnosing ulcerative colitis, while the method of group V involves mixing cells already known to express an HS.111244 mRNA with a test compound to determine whether the test compound decreases gene expression. Consequently, the method steps and reagents are different, making the methods of group IV novel and unobvious over the method of group V.

3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, or Groups III-V, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634
9/30/2002